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COURT OF APPEALS DECISION
DATED AND FILED
May 13, 2003

Appeal No. 02-1939
STATE OF WISCONSIN

ESTATE OF BRIANNA L. KRIEFALL, DECEASED, BY HER SPECIAL ADMINISTRATOR, DOUGLAS A. KRIEFALL, DOUGLAS A. KRIEFALL, CONNIE J. KRIEFALL, AND CHAD KRIEFALL, A MINOR, BY HIS GUARDIAN AD LITEM, WILLIAM M. CANNON, PLAINTIFFS-APPELLANTS,

HUMANA EMPLOYERS HEALTH INSURANCE CO., A WISCONSIN INSURANCE CORPORATION, INVOLUNTARY-PLAINTIFF,

v.

SIZZLER USA FRANCHISE, INC., A FOREIGN CORPORATION, DEFENDANT-THIRD-PARTY PLAINTIFF-CO-APPELLANT,

FEDERAL INSURANCE CO., A FOREIGN INSURANCE CORPORATION, E & B MANAGEMENT CO. WAUKESHA, INC., A WISCONSIN CORPORATION, SECURA INSURANCE, A WISCONSIN INSURANCE CORPORATION, SYSCO SERVICES OF EASTERN WISCONSIN, A WHOLLY OWNED SUBSIDIARY OF SYSCO CORPORATION, A FOREIGN CORPORATION, FIDELITY AND GUARANTY INSURANCE CO., A FOREIGN INSURANCE CORPORATION, LEE M. ESCHENBACH, STEVEN C. BOYSA, AAA INSURANCE CO., AND BBB INSURANCE CO., DEFENDANTS,

EXCEL CORPORATION, A FOREIGN CORPORATION, AND AMERICAN HOME ASSURANCE CO., A FOREIGN INSURANCE CORPORATION, DEFENDANTS-RESPONDENTS,

v.

LEE M. ESCHENBACH, STEVEN C. BOYSA, AAA INSURANCE CO., BBB INSURANCE CO., CARGILL, INC., A FOREIGN CORPORATION, AND EXCEL FOOD DISTRIBUTION, INC., A FOREIGN CORPORATION, THIRD-PARTY DEFENDANTS.

ERVIN J. LESAK AND FLORENCE LESAK, PLAINTIFFS-CO-APPELLANTS,

v.

E & B MANAGEMENT CO. WAUKESHA, INC., DEFENDANT, EXCEL CORPORATION, DEFENDANT-RESPONDENT.

JEFFREY FORTIER, JUDITH FORTIER, TRISTAN FORTIER, AND CARLY FORTIER, PLAINTIFFS-CO-APPELLANTS,

GREAT WEST LIFE & ANNUITY INSURANCE, INVOLUNTARY-PLAINTIFF,

v.

EXCEL CORPORATION, DEFENDANT-RESPONDENT.

KEVIN MCCORMICK, SANDY MCCORMICK, AND KELSEA MCCORMICK, PLAINTIFFS-CO-APPELLANTS,

BLUE CROSS BLUE SHIELD UNITED,
INVOLUNTARY-PLAINTIFF,

v.

EXCEL CORPORATION, DEFENDANT-RESPONDENT.

APPEAL from judgments of the circuit court for Milwaukee County: MICHAEL P. SULLIVAN, Judge. *Reversed.*

Before FINE, SCHUDSON and HOOVER, JJ.

¶ 1 FINE, J.

This is a consolidated appeal from the trial court's grant of summary judgment to Excel Corporation, a meat processor, dismissing claims against Excel for damages allegedly caused by Excel's sale to a Milwaukee area Sizzler restaurant of beef contaminated with the bacterium E. coli O157:H7. The plaintiffs involved in this appeal contend that E. coli bacteria from the meat sold by Excel to the Sizzler restaurant contaminated other food that was eaten by either them or those through whom they derive their claims.[1] Sizzler USA

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[1] The plaintiffs involved in this appeal are: The Estate of Brianna L. Kriefall, Douglas A. Kriefall, Connie J. Kriefall, and Chad Kriefall in Milwaukee County Circuit Court Case No. 00-CV-006463; Ervin J. Lesak and Florence Lesak in Milwaukee County Circuit Court Case No. 00-CV-006360; Jeffrey Fortier, Judith Fortier, Tristan Fortier, and Carly Fortier in Milwaukee County Circuit Court Case No. 00-CV-008756; and Kevin McCormick, Sandy McCormick, and Kelsea McCormick in Milwaukee County Circuit Court Case No. 00-CV-008793. Only the Kriefalls, the Lesaks, and Sizzler USA have filed appellate briefs. A joint *amici curiam* brief has been filed by The American Meat Institute, the National Chicken Council, the National Meat Association, the National Turkey Federation, the

Franchise, Inc., the franchisor of the Milwaukee Sizzler restaurant, is a defendant in some of the actions and also appeals from the trial court's grant of summary judgment dismissing Sizzler USA's claims against Excel. The trial court ruled that the claims against Excel were barred by the federal-preemption doctrine. We disagree and reverse.

I.

¶ 2 In July of 2000, a number of persons were injured and three-year-old Brianna Kriefall died from eating food that everyone party to this appeal, the plaintiffs, Sizzler USA, and Excel, recognize was cross-contaminated by E. coli O157:H7 bacteria from meat sold by Excel. Although some of the parties' arguments on appeal focus on both to what extent the E. coli contamination of the Excel beef was a cause of Brianna's death and the other injuries, and whether Excel was either negligent or sold a dangerously defective product, the only issue we need decide on this appeal is whether the claims against Excel are preempted by federal law. We conclude that federal preemption does not close the doors of Wisconsin's courts to the claims against Excel; the merits of those claims still have to be determined.

¶ 3 Federal preemption is based on Article VI of the United States Constitution, which makes federal law "the supreme Law of the Land." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992). As material here, there are two steps to an analysis of whether federal regulation preempts state common-law claims: (1) whether the controlling federal statute "expressly pre-empts common-law claims," and, if not, (2) whether "the potential conflict between diverse state rules and the federal interest in a uniform system of regulation impliedly pre-empts such claims." *Sprietsma v.*

North American Meat Processors Association, and the Southwest Meat Association. All submissions to this court provided helpful analyses.

Mercury Marine, 537 U.S. 51, 123 S.Ct. 518, 522-523, 154 L.Ed.2d 466 (2002); *see also Geier v. American Honda Motor Co.,* 529 U.S. 861, 869, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000) ("ordinary" preemption principles may bar state claims even though those claims are not expressly preempted by the applicable federal statute).[2]

¶ 4 The interstate sale of beef and other meat products intended for human consumption is regulated by the Federal Meat Inspection Act, 21 U.S.C. §§ 601-695. The Act has a preemption clause, which provides, as applicable here:

> Requirements within the scope of this chapter with respect to premises, facilities and operations of any establishment at which inspection is provided under subchapter I of this chapter [§§ 601-624], which are in addition to, or different than those made under this chapter may not be imposed by any State . . . This chapter shall not preclude any State . . . from making requirement [*sic*] or taking other action, consistent with this chapter, with respect to any other matters regulated under this chapter.

21 U.S.C. § 678.[3] This section thus: (1) prevents states from

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[2] *Sprietsma* also identified a third element, which does not apply here: whether a decision by the agency vested by Congress with regulatory responsibility to not prescribe a safety standard preempts claims seeking to impose liability on a manufacturer in a regulated industry for the manufacturer's failure to adopt that safety standard. 123 S.Ct. at 522-523.

[3] 21 U.S.C. § 678 reads in full:

> Requirements within the scope of this chapter with respect to premises, facilities and operations of any establishment at which inspection is provided under subchapter I of this chapter, which are in addition to, or different than those made under this chapter may not be imposed by any State or Territory or the District of Columbia, except that any such jurisdiction may

impose recordkeeping and other requirements within the scope of section 642 of this title, if consistent therewith, with respect to any such establishment. Marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this chapter may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any establishment under inspection in accordance with the requirements under subchapter I of this chapter, but any State or Territory or the District of Columbia may, consistent with the requirements under this chapter, exercise concurrent jurisdiction with the Secretary over articles required to be inspected under said subchapter I, for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of such an establishment, or, in the case of imported articles which are not at such an establishment, after their entry into the United States. This chapter shall not preclude any State or Territory or the District of Columbia from making requirement [*sic*] or taking other action, consistent with this chapter, with respect to any other matters regulated under this chapter.

We assume, without deciding, that the word "requirements" encompasses state common-law claims, although the law on this is not yet entirely settled. Thus, in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996), the preemption clause provided that, as material here:

"[N]o State . . . may establish or continue in effect with respect to a device intended for human use any requirement —

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

Id., 518 U.S. at 481-482, 116 S.Ct. 2240. Justice John Paul Stevens, writing only for himself and Justices Anthony M. Kennedy, David H. Souter, and Ruth Bader Ginsburg (and not "the" Court, as some of the appellants represent), rejected the view "that any common-law

cause of action is a 'requirement' which alters incentives and imposes duties 'different from, or in addition to,' the generic federal standards that the [Food and Drug Administration] has promulgated in response to mandates under the [Medical Device Amendments of 1976]." *Id..*, 518 U.S. at 486-487, 116 S.Ct. 2240. The same plurality, however, specifically declined to hold "that common-law duties are never 'requirements' within the meaning of the [Medical Device act's preemption clause] and that the statute therefore never pre-empts common-law actions." *Id.*, 518 U.S. at 502, 116 S.Ct. 2240. Four years earlier, however, Justice Stevens, this time writing for himself, Chief Justice William H. Rehnquist, and Justices Byron R. White and Sandra Day O'Connor, opined in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992), that a preemption phrase in that case, which sought damages for the cigarette-related death of the plaintiff's decedent, encompassed state-court claims. *Id.*, 505 U.S. at 520-523, 112 S.Ct. 2608. The phrase provided: "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." *Id.*, 505 U.S. at 515, 112 S.Ct. 2608. Justice Stevens wrote:

> The phrase "[n]o requirement or prohibition" sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules. As we noted in another context, "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."
>
> . . . .
>
> Moreover, common-law damages actions of the sort raised by petitioner are premised on the existence of a legal duty, and it is difficult to say that such actions do not impose "requirements or prohibitions."

Id., 505 U.S. at 521, 112 S.Ct. 2608 (quoted source omitted; bracketing by Justice Stevens). *See also Lynnbrook Farms v.*

imposing "[r]equirements . . . with respect to premises, facilities and operations of any establishment at which inspection is provided under" 21 U.S.C. §§ 601-624 that "are in addition to, or different than those made under" the Act, and (2) permits states to impose "requirement[s]" and to take "other action" that is "consistent" with the Act "with respect to any other matters regulated under" the Act.

¶ 5 For the purpose of this appeal, we assume that all the facts asserted by Excel are true. *See City of Milwaukee v. Burnette,* 2001 WI App 258, ¶ 8, 248 Wis.2d 820, 834, 637 N.W.2d 447, 454 (court reviewing grant or denial of summary judgment ignores disputed facts unless those facts are material to the legal issue to be decided). We analyze whether either 21 U.S.C. § 678 expressly preempts the tort claims asserted here or whether those claims are impliedly preempted by federal law because they present "an actual conflict with a federal objective." *Geier,* 529 U.S. at 871, 120 S.Ct. 1913. Whether state tort claims are preempted by federal law is a legal issue that we review *de novo. International Ass'n of Machinists & Aerospace Workers v. United States Can Co.,* 150 Wis.2d 479, 487, 441 N.W.2d 710, 713 (1989), *cert. denied,* 493 U.S. 1019, 110 S.Ct. 718, 107 L.Ed.2d 738.

Smithkline Beecham Corp., 79 F.3d 620, 627 (7th Cir.1996) ("State tort actions can therefore be as much of a threat to national uniformity as affirmative state regulation.") (relying on Justice Stevens's plurality opinion in *Cipollone,* but mistakenly referring to it as the view of "[t]he Supreme Court"). We also assume, without deciding, that the claims asserted here against Excel would, if successful, affect Excel's "operations" by encouraging or even compelling Excel to change those "operations" in order to avoid future liability caused by E. coli contaminated meat.

II.

¶ 6 Congressional intent concerning the interstate sale of meat is set out in 21 U.S.C. § 602, which we reprint in full:

> Meat and meat food products are an important source of the Nation's total supply of food. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. Unwholesome, adulterated, or misbranded meat or meat food products impair the effective regulation of meat and meat food products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged meat and meat food products, and result in sundry losses to livestock producers and processors of meat and meat food products, as well as injury to consumers. The unwholesome, adulterated, mislabeled, or deceptively packaged articles can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged articles, to the detriment of consumers and the public generally. It is hereby found that all articles and animals which are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate

> such commerce, and to protect the health and welfare of consumers.[4]

(Footnote added.) Thus, as expressed in § 602, Congress wanted to: (1) protect consumers "by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged"; (2) protect those in the meat-production chain from unscrupulous competitors; and (3) "prevent and eliminate burdens upon [interstate or foreign] commerce." *Ibid.* The overriding congressional purpose is, however, public safety — as evidenced by not only the section's direct statements to that effect but also by one of the stated rationales underlying the concurrent congressional desire to preserve fair competition for those who sell wholesome and properly packaged and labeled meat. Accordingly, congressional focus is on ensuring that only meat that is "not adulterated" makes it into the interstate-commerce market. *Ibid.*

¶ 7 The Excel beef that was shipped to the Sizzler restaurant, and according to the plaintiffs caused their illnesses

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[4] "Meat food product" is defined by the Meat Inspection Act as:

> [A]ny product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat food products. This term as applied to food products of equines shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

21 U.S.C. § 601(j).

and Brianna's death, were wrapped "intact" (not ground or chopped or minced or shredded) cuts of sirloin muscle when they left the Excel plant. Excel's preemption argument is based on two main contentions. First, it asserts that the sale of intact meat contaminated with E. coli O157:H7 is not "adulterated" under federal law. Accordingly, under its view, permitting the claims to proceed would prohibit or punish that which federal law allows, thereby running afoul of the preemption clause. Second, it argues that the meat left its plant after it was inspected and approved by government inspectors, and thus, again, permitting these claims against it would, in effect, prohibit or punish that which federal law allows. An evaluation of these contentions requires an analysis of the Meat Inspection Act and the applicable governing regulations.

¶ 8 Most if not all congressional enactments delegate their implementation to one or more administrative agencies. Some statutes have an all-encompassing clause and state "simply that the agency may 'make ... such rules and regulations as may be necessary to carry out the provisions of this Act.'" *See Mourning v. Family Publ'ns Serv., Inc.,* 411 U.S. 356, 369, 93 S.Ct. 1652, 36 L.Ed.2d 318 (1973) (quoting, as an example, § 8 of the United States Housing Act of 1937, as amended, 42 U.S.C. § 1408). When that is the situation, the administrative agency's regulations are followed as long as they are "'reasonably related to the purposes of the enabling legislation.'" *Ibid.* (quoted source omitted). Other delegations of regulatory authority are more limited, and the agency is authorized to promulgate regulations only within narrow confines. In such a situation, the statute, not a regulation that may conflict with the statute, governs, *Touche Ross & Co. v. Redington,* 442 U.S. 560, 577 n.18, 99 S.Ct. 2479, 61 L.Ed.2d 82 (1979) ("[T]he language of the statute and not the rules must control."); *Koshland v. Helvering,* 298 U.S. 441, 447, 56 S.Ct. 767, 80 L.Ed. 1268 (1936) (where "provisions of the act are unambiguous, and its directions specific, there is no power to amend it by regulation"), because "[i]t is axiomatic that an

administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress," *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208, 109 S.Ct. 468, 102 L.Ed.2d 493 (1988).

¶ 9 Congress delegated enforcement of the Meat Inspection Act to the Secretary of the United States Department of Agriculture or designee. 21 U.S.C. §§ 602, 601(a). The Secretary has, in turn, delegated authority under the Meat Inspection Act, with exceptions that are not material here, to the Under Secretary for Food Safety, AGRICULTURE, 7 C.F.R. § 2.18(a)(1)(ii)(B), who, in turn, subdelegated that authority to the Administrator of the Food Safety and Inspection Service, AGRICULTURE, 7 C.F.R. § 2.53(a)(2)(ii).

¶ 10 In contrast to some other delegations of authority by Congress to administrative agencies, Congress's delegation here is focused. Thus, as we will see, although the Secretary has a wide berth in implementing the congressional mandate to inspect meat-processing plants, the Secretary has only limited authority to affect the congressional definition of "adulterated," other than in the area of labeling (21 U.S.C. § 601(m)(5), (7)-(9)). And that limitation, as we will explain, is critical in this case because of Excel's argument that the Secretary views intact meat contaminated with E. coli O157:H7 as not "adulterated."

III.

¶ 11 Whether the claims against Excel are expressly preempted by 21 U.S.C. § 678 because they would impose requirements "with respect to premises, facilities and operations . . . which are in addition to, or different than those made under" the Meat Inspection Act turns on: (1) what is "adulterated" under the Act, and (2) the nature of federal inspection of meat-processing plants under the Act.

A. *The Act's Definition of "Adulterated."*

¶ 12 The word "adulterated" has a special meaning under the Meat Inspection Act, and, significantly, the Secretary is given authority to affect the statute's definition in only one limited instance:

> The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:
>
> (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;
>
> (2)(A) if it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance . . . which may, in the judgment of the Secretary, make such article unfit for human food;
>
> . . . .
>
> (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food; [or]
>
> (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

21 U.S.C. § 601(m). We look at these subsections in turn.

¶ 13 *Subsection (1).* The E. coli strain that killed Brianna and made the others sick is a "deleterious substance which *may*

render [meat] injurious to health." There is no dispute about this. Thus, under the first part of 21 U.S.C. § 601(m)(1), meat that either "bears or contains" E. coli O157:H7 (the "deleterious substance") is "adulterated." That E. coli O157:H7 contamination can be rendered non-"injurious to health" by cooking thoroughly, as discussed below, does not negate this; Congress used the phrase "may render," not "in every circumstance renders." Moreover, if the E. coli bacteria is not considered to be "an added substance," because it comes from some of the animals themselves and is not either applied or supplied during the slaughtering process (although we do not decide this), it cannot be said that the E. coli strain "does not ordinarily render [the meat on or in which it appears] injurious to health." Accordingly, meat contaminated by E. coli O157:H7 is also "adulterated" under the second part of § 601(m)(1).

¶ 14 *Subsection (2)(A).* This section defers to the Secretary (and thus, derivatively, to the Food Safety and Inspection Service) to determine whether the contaminating substance that is alleged to make the affected meat "adulterated" does, in fact, "make such article unfit for human food." As we will see, the Food Safety and Inspection Service determined that E. coli-infected meat is not unfit as human food as long as it is: (1) an intact cut, and (2) treated by cooking or otherwise to kill the surface E. coli contamination.

¶ 15 *Subsection (3).* Meat contaminated by the E. coli strain that was on the Sizzler meat falls within this definition of "adulterated" because the E. coli made the infected meat at least "in part . . . unsound, unhealthful, unwholesome, or otherwise unfit for human food" within the meaning of the all-encompassing phrase "for any other reason."

¶ 16 *Subsection (4).* Meat contaminated by E. coli O157:H7 also falls within this definition of "adulterated" because it is "prepared" in such a way "whereby it may have been rendered injurious to health."

¶ 17 The only regulations defining "adulterated" in the context here are found in ANIMALS AND ANIMAL PRODUCTS, 9 C.F.R. § 301.2:

> *Adulterated.* This term applies to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:
>
> (1) If it bears or contains any such poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;
>
> . . . .
>
> (3) If it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food; [or]
>
> (4) If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

Excel contends that the meat it produced that ultimately went to the Sizzler restaurant was not "adulterated" because the Food Safety and Inspection Service has determined that E. coli adulterates only non-intact meat — that is, meat that is ground or otherwise processed so that the E. coli contamination is not restricted to meat surfaces that are seared, broiled, or otherwise heated to kill the bacteria. To put Excel's argument in context, we examine in detail the Food Safety and Inspection Service's determinations.

¶ 18 In a policy statement published in the Federal Register on January 19, 1999, the Food Safety and Inspection Service opined that it:

> believes that in evaluating beef products contaminated with *E. coli* O157:H7, intact cuts of muscle that are to be distributed for consumption as intact cuts should be distinguished from non-intact products, as well as from intact cuts of muscle that are to be further processed into non-intact product prior to distribution for consumption.

BEEF PRODUCTS CONTAMINATED WITH ESCHERICHIA COLI O157:H7, 64 FED.REG. 2803, 2804 (Jan. 19, 1999). The Inspection Service further explained:

> Non-intact beef products include beef that has been injected with solutions, mechanically tenderized by needling, cubing, Frenching, or pounding devices, or reconstructed into formed entrees (*e.g.,* beef that has been scored to incorporate a marinade, beef that has a solution of proteolytic enzymes applied to or injected into the cut of meat, or a formed and shaped product such as beef gyros). Pathogens may be introduced below the surface of these products as a result of the processes by which they are made. In addition, non-intact beef products include those beef products in which pathogens may be introduced below the surface by a comminution process such as chopping, grinding, flaking, or mincing (*e.g.,* fresh veal sausage and fabricated beef steak).
>
> Intact cuts of beef that are to be further processed into non-intact cuts prior to distribution for consumption must be treated in the same manner as non-intact cuts of beef, since pathogens may be introduced below the surface of these products when they are further processed into non-intact products. Manufacturing trimmings (*i.e.,* pieces of meat

> remaining after steaks, roasts, and other intact cuts are removed) are an example of this type of product. Although manufacturing trimmings may be intact, they are generally further processed into non-intact products.
>
> The Agency believes that with the exception of beef products that are intact cuts of muscle that are to be distributed for consumption as intact cuts, an *E. coli* O157:H7-contaminated beef product must not be distributed until it has been processed into a ready-to-eat product — *i.e.*, a food product that may be consumed safely without any further cooking or other preparation. Otherwise, such products (*i.e.*, non-intact products and intact cuts of muscle that are to be further processed into non-intact products prior to distribution for consumption) must be deemed adulterated. Intact steaks and roasts and other intact cuts of muscle with surface contamination are customarily cooked in a manner that ensures that these products are not contaminated with *E. coli* O157:H7 when consumed. Consequently, such intact products that are to be distributed for consumption as intact cuts are not deemed adulterated.

Ibid. (footnote omitted). The meat sold by Excel arrived at the Sizzler restaurant as wrapped intact cuts of beef that bore labels warning the Sizzler employees to cook the meat thoroughly, to keep the raw meat away from other foods, and to wash working surfaces, tools, utensils, and hands after their contact with raw meat. Excel contends that this, together with the fact that the meat left its plant approved by the federal inspection process, lets it off the hook. There are two problems with this contention.

¶ 19 First, when Excel shipped the meat that was sold to the Sizzler restaurant, meat processors like Excel were required by regulations governing the processors' assessment of food-safety

hazards in their plants to consider "the intended use or consumers of the finished product." ANIMALS AND ANIMAL PRODUCTS, 9 C.F.R. § 417.2(a)(2). This regulation was effective on January 26, 1998, for establishments employing more than 500 persons. PATHOGEN REDUCTION; HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS, 61 FED.REG. 38806, 38869 (July 25, 1996). According to evidence in the record, significantly more than 500 persons worked at the Excel plant when it produced the meat that was sold to the Sizzler restaurant. The scope of this direction to consider the consumers' "intended use" was underscored by the Food Safety and Inspection Service in a policy statement published in the Federal Register on October 7, 2002:

> Even establishments that produce intact product will need to reassess their [hazard-analysis] plans based on the new *E. coli* O157:H7 data [indicating that the bacterium "is more prevalent than was previously thought" "and that this pathogen may he a hazard that is reasonably likely to occur at all stages of handling raw beef products"]. These establishments are required to reassess their [hazard-analysis] plans because much intact beef product may be used to make non-intact product such as ground beef. According to [9 C.F.R.] § 417.2(a)(2), establishments are required to identify the intended use or consumers of the finished product. Therefore, to be able to determine the adequacy of their [hazard-analysis] plans, establishments that produce intact beef products need to determine whether their products will be used to produce raw, non-intact product.

E. COLI O157:H7 CONTAMINATION OF BEEF PRODUCTS, 67 FED.REG. 62325, 62329 (Oct. 7, 2002). Thus, Excel's hazard-analysis plan recognized that its intact cuts of beef were "intended to be sold raw . . . for further processing at retail."

¶ 20 Second, although Congress has in 21 U.S.C. § 601(m)(2)(A) delegated to the Secretary the responsibility to make a "judgment" whether "any . . . added deleterious substance" makes the meat to which the substance is added "unfit for human food," Congress has itself, in 21 U.S.C. § 601(m)(1), (3), & (4), defined "adulterated" without seeking the Secretary's input. As discussed earlier, insofar as the statutory definitions of "adulterated" conflict with the gloss put on them by the Food Safety and Inspection Service, the statutory definition controls. *Touche Ross,* 442 U.S. at 577 n. 18, 99 S.Ct. 2479 ("[T]he language of the statute and not the rules must control."). The focus of subsections (1), (3), and (4) of § 601(m) is on people's health and safety. None of the definitions of "adulterated" in the Act makes a distinction between intact or non-intact meat, and the Food Safety and Inspection Service was powerless to add that distinction to Congress's definitions of "adulterated" in subsections (1), (3), and (4). *See Koshland,* 298 U.S. at 447, 56 S.Ct. 767 (agency has no power to contravene a statute where its "provisions . . . are unambiguous, and its directions specific"). Moreover, as noted, even the Department's own regulations defining the word "adulterated," as opposed to its less-formal pronouncements, make no distinction between contaminated intact meat and contaminated non-intact meat.

¶ 21 Based on the foregoing, we reject Excel's contention that the claims against it are barred because holding it liable for shipping in interstate commerce intact meat contaminated with E. coli O157:H7 would contravene the Act's express "premises, facilities and operations" preemption clause. We now turn to whether the Act's meat-inspection provisions and the regulations promulgated thereunder expressly preempt those claims.

B. *Federal Inspection Under the Act.*

¶ 22 As we have seen, the Meat Inspection Act's preemption clause prohibits states from imposing requirements

"with respect to premises, facilities and operations of any establishment," which, like Excel, are regulated by the Act, that "are in addition to, or different than those made under" the Act. 21 U.S.C. § 678. Again, we assume, without deciding, that the claims asserted here against Excel would, if successful, affect Excel's "operations."

¶ 23 As material to this appeal, 21 U.S.C. § 603(a) governs the inspection of meat and meat food products:

> For the purpose of preventing the use in commerce of meat and meat food products which are adulterated, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all cattle ... before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce ... all as provided by the rules and regulations to be prescribed by the Secretary, as provided for in this subchapter.[5]

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[5] 21 U.S.C. § 603(a) provides in full:

> For the purpose of preventing the use in commerce of meat and meat food products which are adulterated, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all cattle, sheep, swine, goats, horses, mules, and other equines before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce; and all cattle, sheep, swine, goats, horses, mules, and other equines found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other cattle, sheep, swine, goats, horses, mules, or other equines, and when so slaughtered the carcasses of said cattle, sheep, swine, goats, horses, mules, or other equines shall be subject to

(Footnote added.) Effective January 26, 1998, for meat processors with more than 500 employees, the Food Safety and Inspection Service delegated to the meat processors themselves the responsibility of coming up with procedures, designated as a Hazard Analysis and Critical Control Point system, adapted to the processors' own circumstances, to safeguard the wholesomeness of the meat they produce:

> Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

9 C.F.R. § 417.2(a)(1); PATHOGEN REDUCTION, 61 FED.REG. at 38869. As further summarized by the Department in a June 2000 report issued by its Office of Inspector General, the new program was designed to "reverse[ ]" the arrangement under which "the production of meat and poultry products was monitored at every stage by Government employees" to a system that "allow[ed] a plant to monitor itself." U.S.D.A. REP. NO. 24001-3-At, at 1 (2000). Thus, the new plan, as phrased by the report, "gave industry, not Government, the primary responsibility for ensuring the safety of meat and poultry products." *Ibid.*

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a careful examination and inspection, all as provided by the rules and regulations to be prescribed by the Secretary, as provided for in this subchapter.

¶ 24 In a report dated July 25, 1996, the Food Safety and Inspection Service detailed the nature of the extensive inspection overhaul:

> The Food Safety and Inspection Service is establishing requirements applicable to meat and poultry establishments designed to reduce the occurrence and numbers of pathogenic micro-organisms on meat and poultry products, reduce the incidence of foodborne illness associated with the consumption of those products and provide a new framework for modernization of the current system of meat and poultry inspection. The new regulations (1) require that each establishment develop and implement written sanitation standard operating procedures; (2) require regular microbial testing by slaughter establishments to verify the adequacy of the establishments' process controls for the prevention and removal of fecal contamination and associated bacteria; (3) establish pathogen reduction performance standards for Salmonella that slaughter establishments and establishments producing raw ground products must meet; and (4) require that all meat and poultry establishments develop and implement a system of preventive controls designed to improve the safety of their products, known as [Hazard Analysis and Critical Control Point systems].

PATHOGEN REDUCTION, 61 FED.REG. at 38806 (acronyms omitted). E. coli O157:H7 is a bacterium associated with "fecal contamination." *Id.* at 38837. The report noted that the overhaul was triggered by "[r]ecent outbreaks of foodborne illness and studies conducted over the past decade ... [that] have established the need for fundamental change in the [Food Safety and Inspection Service] meat and poultry inspection program to improve food safety, reduce the risk of foodborne illness in the United States, and make better use of the Agency's resources." *Id.* at 38807 (acronyms omitted).

¶ 25 The Service also explained that the Hazard Analysis and Critical Control Point systems "focus on attributes affecting product safety, not those affecting economic adulteration or quality" and that it was "a conceptually simple system whereby meat and poultry establishments can identify and evaluate the food safety hazards that can affect the safety of their products, institute controls necessary to prevent those hazards from occurring or keeping them within acceptable limits, monitor the performance of controls, and maintain records routinely." *Id.* at 38814. Among the matters that meat processors had to consider in establishing an applicable Hazard Analysis and Critical Control Point plan for their facilities were:

> (1) What potential hazards may be present in the animals to be slaughtered or the raw materials to be processed? (2) What are the avenues that might lead to contamination of finished product with pathogenic microorganisms, hazardous chemicals, or other potentially hazardous contaminants? (3) What is the likelihood of such contamination and what are the means for preventing it? (4) Does the food contain any ingredient historically associated with a known microbiological hazard? (5) Does the food permit survival or multiplication of pathogens or toxin formation during processing? (6) Does the process include a controllable processing step that destroys pathogens? (7) Is it likely that the food will contain pathogens and are they likely to increase during the times and conditions under which the food is normally stored before being consumed? (8) What product safety devices are used to enhance consumer safety (e.g., metal detectors, filters, thermocouples)? (9) Does the method of packaging affect the multiplication of pathogenic microorganisms and/or the formation of toxins? (10) Is the product epidemiologically linked to a foodborne disease?

Id. at 38815. The Service also focused specifically on E. coli contamination:

> In slaughter establishments, fecal contamination of carcasses is the primary avenue for contamination by pathogens. Pathogens may reside in fecal material and ingesta, both within the gastrointestinal tract and on the exterior surfaces of animals going to slaughter. Therefore, without care being taken in handling and dressing procedures during slaughter and processing, the edible portions of the carcass can become contaminated with bacteria capable of causing illness in humans. Additionally, once introduced into the establishment environment, the organisms may be spread from carcass to carcass.
>
> Because the microbial pathogens associated with fecal contamination are the single most likely source of potential food safety hazard in slaughter establishments, preventing and removing fecal contamination and associated bacteria are vital responsibilities of slaughter establishments. Further, because such contamination is largely preventable, controls to address it will be a critical part of any slaughter establishment's [Hazard Analysis and Critical Control Point] plan. Most slaughter establishments already have in place procedures designed to prevent and remove visible fecal contamination.
>
> There is general agreement within the scientific community that generic E. coli is the best single microbial indicator for fecal contamination. [The Food Safety and Inspection Service], therefore, is requiring that establishments slaughtering livestock or poultry begin testing for E. coli.

Id. at 38837. The upshot of all this is that Excel and the rest of the meat-processing industry were well aware of both the

danger to health posed by E. coli contamination and the need for their Hazard Analysis and Critical Control Point plans to address eliminating that contamination in their respective facilities. Indeed, the dangers were deemed to be so significant that the Food Safety and Inspection Service saw as the goal of a facility's Hazard Analysis and Critical Control Point System the *prevention* of fecal contamination:

> Establishments that slaughter livestock and poultry currently have an obligation to control the slaughter and sanitary dressing process so that contamination with fecal material and other intestinal contents is prevented. This means that establishments must maintain sanitary conditions and use good manufacturing practices to avoid contamination with visible feces and ingesta and associated bacteria.

Id. at 38838. The Service recognized, however, that mere visible inspection was insufficient:

> [Food Safety and Inspection Service] inspectors apply a zero tolerance performance standard for visible feces and ingesta on dressed carcasses. As a practical matter, however, *additional measures must be taken if inspectors are to assess the extent to which the invisible bacteria associated with feces and ingesta may be present on the carcass.*
>
> [The Food Safety and Inspection Service] has concluded, based on its proposal and the comments received, that the current practice of organoleptic examination by inspectors and the physical removal of visible contamination by establishments needs to be supplemented with an establishment-conducted microbial verification activity. This microbial testing is designed to verify, for the establishment and [the Food Safety and Inspection Service], that the establishment has controlled its slaughter process

> with respect to *prevention and removal* of fecal material and ingesta *and* associated bacteria.

Ibid. (emphasis added).[6] The Food Safety and Inspection Service characterized the goal as requiring "a slaughter establishment's adherence to zero tolerance for fecal contamination." *Id.* at 38850. Indeed, in a report published in the Federal Register on October 7, 2002, the Service repeated that it "considers an acceptable reduction for *E. coli* O157:H7 to be a reduction to an undetectable level." E. coli O157:H7, 67 FED.REG. at 62329.

¶ 26 Significantly, in light of Excel's focus on the distinction between intact cuts of beef, which were sold to the Milwaukee Sizzler, and non-intact beef, the Service's statement that E. coli contamination must be reduced to "an undetectable level" appears on the same page of the Federal Register reiterating the already in-place requirement in 9 C.F.R. § 417.2(a)(2) that meat processors identify and consider "the intended use or consumers of the finished product." E. COLI O157:H7, 67 FED.REG. at 62329. Even in 1996, however, the Food Safety and Inspection Service recognized that "foodborne illness" was "a substantial and intolerable public health problem" and explained why it was so important for processors to consider what would happen to even intact meat after it left the processors' plants:

> [T]he health effects of enteric pathogens are relatively well documented. If the pathogens enter the food supply, they do, under certain conditions, cause foodborne illness. If their presence can be prevented, no amount of temperature abuse, mishandling or undercooking can lead to foodborne illness.

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[6] "Organoleptic" is defined as "affecting or making an impression upon one or more of the organs of special sense." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1590 (1993).

PATHOGEN REDUCTION, 61 FED.REG. at 38962. Given the realities of what it saw as consumers' food-handling patterns, the Food Safety and Inspection Service bored in on the only effective way to reduce or eliminate food-borne illness:

> Occurrence of foodborne disease is a multi-step process. The first, and critical, step is the introduction of a pathogen into or onto the raw product. If a pathogen is present, then subsequent temperature abuse or mishandling may permit bacterial counts to increase to levels which increase the likelihood that illness will occur; mishandling may result in cross- contamination of other foods which are not cooked before being eaten; or improper cooking may not kill all pathogenic bacteria present in the product. In these instances, it may be said that the illness was "caused" by improper handling. However, *disease would not have occurred if the pathogen had not been present on the raw product in the first place.*

Id. at 38966 (emphasis added). We now turn to how all this affects whether the claims against Excel are barred by the express-preemption clause.

IV.

¶ 27 We start our analysis, as we must, with the words of the statute. In discerning whether Congress intended the Meat Inspection Act to preempt state claims we must give to unambiguous statutory language the meaning it denotes. *Sprietsma,* 123 S.Ct. at 526, 123 S.Ct. 518 (statute's "'plain wording'" of preemption clause "'necessarily contains the best evidence of Congress' pre-emptive intent'") (quoted source omitted). This is also the general rule of statutory construction in Wisconsin. *Anderson v. City of Milwaukee,* 208 Wis.2d 18, 25, 559 N.W.2d 563, 566 (1997) (legislative intent discerned from statute's plain language); *Jungbluth v. Hometown, Inc.,*

201 Wis.2d 320, 327, 548 N.W.2d 519, 522 (1996) (plain statutory language is applied as it is written).

¶ 28 Although our analysis is governed by the statute's words, interpretation and application of preemption "language does not occur in a contextual vacuum," but must be "informed by two presumptions about the nature of pre-emption." *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996). First, the United States Supreme Court has "long presumed that Congress does not cavalierly pre-empt state-law causes of action," and thus the Court "'start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Ibid.* (quoted source omitted). Further, this presumption against preemption applies to not only "whether Congress intended any pre-emption at all," but also to the scope of any preemption that Congress may have intended. *Ibid.*

¶ 29 Second, the "'purpose of Congress is the ultimate touchstone' in every pre-emption case." *Ibid.* (quoted source omitted). As we have seen, Congressional intent "primarily is discerned from the language of the pre- emption statute and the 'statutory framework' surrounding it," and, also, "the 'structure and purpose of the statute as a whole' as revealed not only in the text but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Id.,* 518 U.S. at 485-486, 116 S.Ct. 2240 (quoted source and internal citations omitted).

A.

¶ 30 The express preemption clause here prohibits any state from imposing on producers regulated by the Meat Inspection Act any "[r]equirements within the scope of [the Act] with respect to premises, facilities and operations . . . which are in addition to, or different than those made under" the Act. 21 U.S.C. § 678. There is, however, a savings clause that, as we

have also seen, permits states to "make[ ] requirement[s] or tak[e] other action, consistent with [the Act], with respect to any other matters regulated under this [Act.]" *Ibid.*

¶ 31 On its surface, the phrase "with respect to premises, facilities and operations" applies only to the physical plant, the type and quantity of various categories of equipment, and the method of running the business. Thus, without deciding this, it seems to us that a state law that required a meat processor to employ a certain number of quality-control personnel or to irradiate its meat would fall within the express-preemption provision. But it is one thing to view the scope of the preemption clause to encompass meat inspection, meat treatment, or, indeed, the entire reach of the Hazard Analysis and Critical Control Point program, and entirely different to hold that state claims based on the sale of meat contaminated with E. coli O157:H7 are preempted by the clause. *Medtronic* makes this clear.

¶ 32 *Medtronic* concerned a suit for damages sustained by a person injured by an allegedly negligently manufactured and defective pacemaker part. *Id.*, 518 U.S. at 480-481, 116 S.Ct. 2240. The preemption clause there was similar to the one here, and provided, as material:

> "[N]o State ... may establish or continue in effect with respect to a device intended for human use any requirement —
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

Id., 518 U.S. at 481-482, 116 S.Ct. 2240. *Medtronic* held that the claims in that case were not preempted because the

"violations of common-law duties" for which the damages were sought were either "parallel" to the requirements set out in the federal statute, or more narrow than those requirements. *Id.*, 518 U.S. at 495, 116 S.Ct. 2240. *Medtronic* explained:

> Nothing in [the preemption clause] denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of Florida law to prove that these violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be "different from" the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule. The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.

Ibid. A similar analysis governs this case.

¶ 33 No one disputes but that the major goal of the Meat Inspection Act is to prevent the sale of "adulterated" meat products. As we have explained in Part III.A. of this opinion, the Excel meat that was sold to the Sizzler restaurant was "adulterated" as Congress defined that word, even though the meat left the Excel facility as intact cuts. Thus, a claim premised on damages resulting from the sale of "adulterated" meat, in the words of *Medtronic,* "merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Ibid.*

¶ 34 By the same token, and as seen in Part III.B. of this opinion, a goal of the Food Safety and Inspection Service and the Hazard Analysis and Critical Control Point plans it implements is to "prevent" fecal and E. coli contamination--what the agency called "zero tolerance" for fecal contamination and the concomitant reduction of the E. coli bacterium to an "undetectable level." PATHOGEN REDUCTION, 61 FED.REG. at 38850; E. COLI O157:H7, 67 FED.REG. at 62329. Here also, in the words of *Medtronic,* claims based on allegations that Excel meat sold to the Sizzler restaurant had detectable levels of E. coli contamination "merely provide[ ] another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Medtronic,* 518 U.S. at 495, 116 S.Ct. 2240. Indeed, the Hazard Analysis and Critical Control Point program leaves it largely to the processors themselves to determine how best to achieve the goals of zero tolerance for bacteria-laden fecal matter and undetectable levels of E. coli O157:H7. Thus, a processor's responsibility to produce wholesome, non-pathogenic meat is, under the Act's inspection- mandate and the interpretation of the Food Safety and Inspection Service of that mandate, parallel to and not divergent from the processor's goal of avoiding tort-claims liability.

¶ 35 Furthermore, insofar as the preemption doctrine implicates a federal need for uniformity of regulation, *see Sprietsma,* 123 S.Ct. at 523, the federal inspection scheme here *eschews* uniformity in favor of non-uniform plant-by- plant Hazard Analysis and Critical Control Point plans developed by the plant operators themselves. Simply put, rather than a nation-wide uniform, one-size- fits-all approach present in so many preemption cases, the Food Safety and Inspection Service now lets meat processing plants monitor themselves with only comparatively minimal federal oversight. PATHOGEN REDUCTION, 61 FED.REG. at 38852 ("The Agency is responsible for establishing and enforcing reasonable standards; it intends to give the industry the maximum flexibility to decide how best

to meet such standards. It does not intend to regulate or prescribe how the standards are to be met.").

¶ 36 Thus, the potential success of the claims asserted here against Excel because of its alleged failure to reach the goal of non-detectable E. coli contamination set by the Food Safety and Inspection Service is not a "requirement" either "in addition to, or different than" requirements established under the Meat Inspection Act "with respect to premises, facilities and operations"; rather, it is wholly consistent with the predominant intent of the Act, which is to keep health-threatening meat out of the commerce stream. Therefore, the state claims are adjunct to, rather than a displacement of, the standards enacted by Congress and the conforming regulations promulgated by the Secretary. Permitting assertion of those claims supplements, in a way consistent with the "touchstone" of Congressional intent, the federal goal to remove pathogen-laden meat from the food supply.

¶ 37 The record here demonstrates in a concrete way how the claims asserted against Excel supplement protection afforded by the meat-inspection program and what the Food Safety and Inspection Service has recognized are the significant limitations of the "organoleptic examination by inspectors." *Id.* at 38838. Only two federal inspectors oversee a meat fabrication area in Excel's plant where several hundred workers daily cut the approximately seven-foot-long, 350-pound split carcasses into some 8,000 intact cuts of beef weighing approximately two to four or three to five pounds each. Federal inspectors do not inspect each one of these smaller cuts of beef. Moreover, the seven-foot-long carcasses arrive at the fabrication area after whizzing by the Service inspection station at the rate of one side every six seconds.

¶ 38 In sum, since, the "'purpose of Congress is the ultimate touchstone' in every pre-emption case," *Medtronic,* 518 U.S. at 485, 116 S.Ct. 2240 (quoted source omitted), and since the claims asserted against Excel are wholly congruent with the

overarching purpose of the Meat Inspection Act, and in light of the savings clause, which, as we have seen, permits states to "make [ ] requirement[s] or tak[e] other action, *consistent* with [the Act], with respect to any other matters regulated under this [Act]" (emphasis added), we hold that those claims are not preempted by the express-preemption clause in 21 U.S.C. § 678.[7]

B.

¶ 39 As noted, "ordinary" preemption principles may bar state claims even though those claims are not expressly preempted by the applicable federal statute. *Geier,* 529 U.S. at 869, 120 S.Ct. 1913. The prerequisite to finding an implied preemption, however, is "an actual conflict with a federal objective." *Id.,* 529 U.S. at 871, 120 S.Ct. 1913. As already explained at some length, there is no "actual conflict" here; permitting claims against Excel for putting into the stream of commerce meat that was contaminated with E. coli O157:H7 is consistent with the objective of the Meat Inspection Act--the sale in interstate commerce of safe, wholesome meat. Accordingly, there is no implied preemption. *See Sprietsma,* 123 S.Ct. at 522-523.

V.

¶ 40 There are two final matters we must discuss.

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[7] During oral argument, Excel forcefully contended that a failure to apply federal preemption will subject the meat-processing industry to intractable dilemmas. But all manufacturers confront difficult cost/benefit choices when balancing expense and methods of production on the one hand, against, on the other hand, potential liability for injuries that may be caused by their products; we see no special burden on Excel or other meat processors beyond that faced by anyone who puts potentially dangerous products into the stream of commerce.

A.

¶ 41 Excel's briefs rely heavily on *Boulahanis v. Prevo's Family Market, Inc.*, 230 Mich.App. 131, 583 N.W.2d 509 (1998), *cert. denied,* 530 U.S. 1203, 120 S.Ct. 2194, 147 L.Ed.2d 232, which held that the Meat Inspection Act preempted state claims for a death and injuries caused by the sale of ground beef contaminated with E. coli O157:H7. The trial court also relied heavily on *Boulahanis* in deciding to grant summary judgment to Excel. Accordingly, we now turn to that case, which, in our view, is irrelevant to our decision.

¶ 42 In *Boulahanis,* the contaminated meat was purchased in 1993, before the United States Department of Agriculture determined that the E. coli bacterium was dangerous. *Id.*, 583 N.W.2d at 512. The plaintiffs contended that their claims could not be preempted because the Department had not promulgated any regulations concerning the sale of E. coli-infected meat when the meat was purchased, and thus there could be no "conflict with then-existing federal law." *Ibid. Boulahanis* rejected that argument, holding that the Department's "intentional decision not to regulate the presence of E. Coli because it was not considered an adulterant carries the force of positive enactment." *Ibid.* Thus, under *Boulahanis's* view, holding the "defendants liable for failing to detect the presence of E. Coli bacteria in the meat purchased by plaintiffs in 1993 would run contrary to the [Department]'s then-existing determination that inspection for E. Coli bacteria was not required." *Ibid.*

¶ 43 Aside from its other infirmities, including its paucity of analysis, *Boulahanis's* rationale for finding preemption — agency *in* action — is, without a deeper analysis than *Boulahanis* made, questionable in light of *Sprietsma,* which held that although agency inaction could be evidence of a federal mandate to leave an area unregulated, it also could be, and was held in *Sprietsma* to be, "fully consistent with an intent to preserve state regulatory authority pending the adoption of

specific federal standards." *Sprietsma,* 123 S.Ct. at 527-528. Moreover, contrary to the situation in *Boulahanis,* the Food Safety and Inspection Service is now not only concerned with E. coli O157:H7, but, indeed, is striving to reduce its presence in meat sold as human food to, as we have seen, "undetectable levels." *Boulahanis* gives us no guidance.

B.

¶ 44 Although it is hardly dispositive, for the reasons we explain below, the Food Safety and Inspection Service has assumed that tort claims against meat processors are *not* preempted by the Meat Inspection Act.

¶ 45 As we have seen, the Service issued a lengthy report dated July 25, 1996, which explained its proposed Hazard Analysis and Critical Control Point plan and set out proposed implementing rules. The report also noted concerns expressed by some of those with whom it had consulted. Responding to a concern raised by "[a] few commenters . . . about product liability due to product recalls stemming from test results," the Service explained: "Establishments' liability to civil lawsuits should not be adversely affected by this rule precisely because it is an establishment's process, not individual lots of product, that is being assessed, for inspection purposes, on the basis of this testing." PATHOGEN REDUCTION, 61 FED.REG. at 38854. Moreover, the Service opined that if meat producers "did not suffer legal consequences" as a result of selling pathogen-infested meat, it was because "[c]onsumers often cannot trace a transitory illness [caused by pathogenic microorganisms] to any particular food or even be certain it was caused by food." *Ibid.*

¶ 46 Nowhere in the July 25, 1996, report did the Service even hint that it considered tort claims against meat processors to be preempted by the Meat Inspection Act, and we are aware of no other place where it has so opined. We mention all this in passing, however, because it is far from settled that an agency's view of the preemptive effect of a statute is given *any*

deference. Indeed, the United States Supreme Court has assumed that the agency's view is entitled to *no* deference. *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 744, 116 S.Ct. 1730, 135 L.Ed.2d 25 (1996) (assuming, but not deciding, that "whether a statute is pre-emptive . . . must always be decided *de novo* by the courts"). *See also Commonwealth of Massachusetts v. United States Dep't of Transp.*, 93 F.3d 890, 892-897 (D.C.Cir.1996) (recognizing *Smiley*, discussing deference to the agency and holding contrary to the agency's view).

VI.

¶ 47 We reverse the summary judgments granted to Excel dismissing the claims of the Kriefalls, the Lesaks, the Fortiers, the McCormicks, and Sizzler USA.[8]

By the Court. — Judgments reversed.

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[8] In light of our holding that the claims asserted against Excel are not preempted by federal law, we do not address the additional argument that Excel waived by contract its right to rely on the preemption doctrine. *See Gross v. Hoffman*, 227 Wis. 296, 300, 277 N.W. 663, 665 (1938) (only dispositive issue need be addressed); *State v. Blalock*, 150 Wis.2d 688, 703, 442 N.W.2d 514, 520 (Ct.App.1989) (cases should be decided on the "narrowest possible ground").

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REMITTITUR Date: September 12, 2003

District 1
Case No. 02-1939
Circuit Court Case No. 00 CV 6463, 00 CV 6360, 00 CV 8756, 00 CV 8793

Estate of Brianna L. Kriefall, deceased, by her Special Administrator, Douglas A. Kriefall, Douglas A. Kriefall, Connie J. Kriefall, and Chad Kriefall, a minor, by his Guardian ad Litem, William M. Cannon,
Plaintiffs-Appellants,
Humana Employers Health Insurance Co., a Wisconsin insurance corporation,
Involuntary-Plaintiff,

v.

Sizzler USA Franchise, Inc., a foreign corporation,

Defendant-Third-Party Plaintiff-Co-Appellant,

Federal Insurance Co., a foreign insurance corporation, E&B Management Co. Waukesha, Inc., a Wisconsin corporation, Secura Insurance, a Wisconsin insurance corporation, Sysco Services of Eastern Wisconsin, a wholly owned subsidiary of Sysco Corporation, a foreign corporation, Fidelity and Guaranty Insurance Co., a foreign insurance corporation, Lee M. Eschenbach, Steven C. Boysa, AAA Insurance Co., and BBB Insurance Co.,

Defendants,

Excel Corporation, a foreign corporation, and American Home Assurance Co., a foreign insurance corporation,

Defendants-Respondents,

v.

Lee M. Eschenbach, Steven C. Boysa, AAA Insurance Co., BBB Insurance Co., Cargill, Inc., a foreign corporation, and Excel Food Distribution, Inc., a foreign corporation,

Third-Party Defendants.

Ervin J. Lesak and Florence Lesak,

Plaintiffs-Co-Appellants,

v.

E&B Management Co. Waukesha, Inc.,

Defendant,

Excel Corporation,
Defendant-Respondent.

Jeffrey Fortier, Judith Fortier, Tristan Fortier,
and Carly Fortier,
Plaintiffs-Co-Appellants,
Great West Life & Annity Insurance,
Involuntary-Plaintiff,

v.

Excel Corporation,
Defendant-Respondent.

Kevin McCormick, Sandy McCormick, and
Kelsea McCormick,
Plaintiffs-Co-Appellants,
Blue Cross Blue Shield United,
Involuntary-Plaintiff,

v.

Excel Corporation,
Defendant-Respondent.

John Barrett, Circuit Court Clerk
Appeals Processing Division
901 N. 9th Street, Room G-8
Milwaukee, WI 53233

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This cause was an appeal to review the judgment(s) and order(s) of the Circuit Court of Milwaukee County.

IT IS ORDERED AND ADJUDGED by this court in an opinion filed on May 13, 2003, that:

Judgments reversed.

Panel: Hon. Ralph Adam Fine
Hon. Charles B. Schudson
Hon. Michael W. Hoover

The appeal record is hereby returned to the Clerk of the Circuit Court for Milwaukee County.

I certify that the above is a correct transcript of the original order and judgment of the court in the above cause.

Cornelia G. Clark
Clerk of Court of Appeals

OFFICE OF THE CLERK
SUPREME COURT OF WISCONSIN
110 EAST MAIN STREET, SUITE 215
P.O. BOX 1688
MADISON, WISCONSIN 53701-1688
TELEPHONE: 608-266-1880
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September 12, 2003

To:

Hon. Michael P. Sullivan
Milwaukee County Circuit Court
901 N. Ninth Street
Milwaukee, WI 53233

John Barrett
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(Additional Addresses on Page Two)

You are hereby notified that the Court has entered the following order:

No. 02-1939 Estate of Brianna L. Kriefall v. Sizzler U SA, et al., L.C. #s 00CV6463, 00CV6360, 00CV8756, 00CV8793

A petition for review pursuant to Wis. Stat. § 808.10 having been filed on behalf of defendant-respondent-petitioner, Excel Corporation, and a motion of the American Meat Institute, et al. for permission to file an *amicus curiae* brief, and considered by this court;

IT IS ORDERED that the motion is granted and the *amicus curiae* brief is accepted for filing.

IT IS FURTHER ORDERED that the petition for reveiw is denied, with $50 costs to be divided equally among respondents.

Wilcox, J., did not participate.

Cornelia G. Clark
Clerk of Supreme Court

Additional Addresses:

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STATE OF WISCONSIN
CIRCUIT COURT, MILWAUKEE COUNTY
Re: In re Consolidated *E. coli* 0157:H7 Cases
Case Nos. 00-CV-006503
00-CV-006327
00-CV-006422
00-CV-006367
00-CV-006466
00-CV-006437
00-CV-006412
00-CV-008756
00-CV-008793
00-CV-006360
00-CV-006463

DECISION ON EXCEL CORPORATIONS

MOTION FOR SUMMARY JUDGMENT

Excel Corporation ("Excel"), the meat processor defendant in the above cases, moves for summary judgment of dismissal of plaintiffs claims against it. I grant Excel's motion for two reasons. First, I agree with Excel that Congress has delegated to the USDA the exclusive role of determining when meat is safe and unadulterated. Second, Excel has not contractually waived its federal preemption arguments as to the plaintiffs' claims.

For roughly one hundred years in this country, Congress has regulated the distribution of meat products in interstate commerce. This is the direct legacy of muckrakers like Upton Sinclair, the author of *The Jungle*. Sinclair, a socialist, was said to have lamented later in life that he aimed his novel at America's heart, but instead hit her in the stomach. His novel vilified the meat industry in this country and helped bring about reforms that resulted in the extensive regulatory scheme present in our country today. Congress has delegated that regulatory role to the USDA. See 21 U.S.C. sec. 601 *et seq.* Part of the

USDA's job is to determine when meat is "safe, wholesome, and not adulterated." *Armour & Co. v. Ball*, 468 F.2d 76, 81 (6th Cir., 1972). Intact meat containing surface E coli 0157:H7 bacteria is not considered adulterated under federal law because the bacteria is destroyed when the surface of the intact cuts are broiled in establishments like Sizzler's Steak House. See 64 Fed. Reg. 2803, 2804 (1999).

> "Intact steaks, and other intact cuts of muscle with surface contamination are customarily cooked in a manner that ensures that these products are not contaminated with E. coli 0157:H7 when consumed. Consequently, such intact products that are to be distributed for consumption as intact cuts are not deemed adulterated."

Congress has expressly preempted the states from establishing meat standards different from the federal ones. 21 U.S.C. sec. 678 states:

> "Requirements . . . with respect to premises, facilities and operations of any establishment . . . which are in addition to, or different than those made under this chapter may not be imposed by any State . . . Marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this chapter may not be imposed by any State . . ."

This express preemption provision overcomes any state law to the contrary. *Boulahanis v. Prevo's Family Market, Inc.*, 583 N.W.2d 509, 511-12 (Mich. App. 1998), cert. denied, 530 U.S. 1203 (1998).

The policy behind preemption in this area makes sense. Excel's processing plant is an "official establishment" governed by the Federal Meat Inspection Act. The federal government has acted in this area to provide national standards so that properly handled and cooked meat products are safe for human consumption. These standards protect the meat processors also, so that they know what is expected of them in regard to their

products that are distribute [sic] among the many states. In an area of such great national concern, it is essential that the rules be uniform. Federal inspectors are in these meat plants, testing the meat and monitoring the processing programs of companies like Excel. The federal regulatory scheme is so long-standing and so comprehensive that I conclude it preempts any state laws to the contrary. That includes bringing civil suits against meat processors like Excel.

Nor did Excel contract away its right to rely on federal preemption. First of all, warranty claims require privity, and the plaintiffs here were not in privity with Excel in the 2000 sale. *Twin Disc, Inc. v. Big Bud Tractor, Inc.*, 582 F. Supp. 208, 215 (E.D. Wisc. 1984). Excel sold its meat to Sysco, who in turn sold it to the franchisee, E&B. Second, Sysco's purchase of the meat in question was governed by an agreement dated January 11, 2000. That agreement contained a clause stating that the document ". . . contains the entire agreement between the parties and cannot be varied orally and sh all be binding on the heirs, successors and assigns of the parties." This "merger clause" effectively does away with the 1993 and 1997 "contracting away" documents relied on by the opposition to the motion.

It is important to note that this decision does not deny these plaintiffs their day in court. They may continue to proceed against the restaurant whose employees handled the food as well as against the restaurant's national franchisor, who is alleged to have improperly trained and supervised it[s] local franchisee. But they may not sue Excel.

Counsel for the prevailing party shall prepare and submit the appropriate under the local five-day rule.

Dated: May 15, 2002.

By the Court:

/s/Michael P. Sullivan
Michael P. Sullivan
Circuit Judge

STATE OF WISCONSIN
CIRCUIT COURT, MILWAUKEE COUNTY

In re Consolidated *E. coli* 0157:H7 Cases
Case Nos. 00-CV-006503
00-CV-006327
00-CV-006422
00-CV-006367
00-CV-006466
00-CV-006437
00-CV-006412
00-CV-008756
00-CV-008793
00-CV-006360
00-CV-006463

Case Code. 30107 - Personal Injury, Other

ORDER GRANTING
EXCEL CORPORATION'S
MOTION FOR SUMMARY JUDGMENT

This matter came before the Court on Excel Corporation's Motion for Summary Judgment seeking to dismiss plaintiffs' claims against Excel Corporation as a matter of law. The Motion was fully briefed, and argued on March 25, 2002.

The Court considered the written submissions and oral arguments. For the reasons set forth in the Court's May 15, 2002 written Decision on Excel Corporation's Motion for Summary Judgment, plaintiffs' claims fail as a matter of law.

Further, the effect of the Court's May 15, 2002 written Decision requires the dismissal of the cross-claims asserted by Sizzler USA Franchise Inc. against Excel Corporation and its business unit, Excel Food Distribution Company.

THEREFORE, IT IS ORDERED that Excel Corporation's Motion for Summary Judgment is GRANTED, and judgment is hereby rendered in favor of Excel Corporation on plaintiffs'

claims. Plaintiffs' claims against Excel Corporation are hereby dismissed with prejudice.

IT IS FURTHER ORDERED that Sizzler USA Franchise Inc.'s cross-claims asserted against Excel Corporation and its business unit, Excel Food Distribution Company are hereby dismissed with prejudice.

Dated at Milwaukee, Wisconsin this 19th day of June, 2002.

/s/ Michael P. Sullivan
Michael P. Sullivan
Circuit Court Judge

STATE OF WISCONSIN
CIRCUIT COURT, MILWAUKEE COUNTY

In re Consolidated *E. coli* 0157:H7 Cases
Case Nos. 00-CV-006503
00-CV-006327
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00-CV-006412
00-CV-008756
00-CV-008793
00-CV-006360
00-CV-006463
Case Code: 30107 - Personal Injury, Other

JUDGMENT

Pursuant to the Court's Order dated June 19, 2002;

IT IS HEREBY ADJUDGED THAT:

1. Excel Corporation's Motion for Summary Judgment is granted and judgment is entered in favor of Excel Corporation on plaintiffs' claims. Plaintiffs' claims against Excel Corporation are dismissed with prejudice.

2. Sizzler USA Franchise Inc.'s cross-claims asserted against Excel Corporation and its business unit, Excel Food Distribution Company are dismissed with prejudice.

Judgment entered July 16, 2002.

By the Court
John Barrett
Clerk of Circuit Court
By /s/Diane Gawronski
Judgment Clerk

21 U.S.C. § 601. **Definitions**

As used in this chapter, except as otherwise specified, the following terms shall have the meanings stated below:

* * *

(m) The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

> (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;
>
> (2)(A) if it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food;
>
> (B) if it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 346a of this title,
>
> (C) if it bears or contains any food additive which is unsafe within the meaning of section 348 of this title,

(D) if it bears or contains any color additive which is unsafe within the meaning of section 379e of this title: Provided, That an article which is not adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by regulations of the Secretary in establishments at which inspection is maintained under this subchapter;

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) if it is, in whole or in part, the product of an animal which has died otherwise than by slaughter;

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title;

(8) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been

substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is; or

(9) if it is margarine containing animal fat and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance.

21 U.S.C. § 602. **Congressional statement of findings**

Meat and meat food products are an important source of the Nation's total supply of food. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. Unwholesome, adulterated, or misbranded meat or meat food products impair the effective regulation of meat and meat food products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged meat and meat food products, and result in sundry losses to livestock producers and processors of meat and meat food products, as well as injury to consumers. The unwhclesome, adulterated, mislabeled, or deceptively packaged articles can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged articles, to the detriment of consumers and the public generally. It is hereby found that all articles and animals which are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

21 U.S.C. § 621. **Inspectors to make examinations provided for; appointment; duties; regulations**

The Secretary shall appoint from time to time inspectors to make examination and inspection of all cattle, sheep, swine, goats, horses, mules, and other equines, inspection of which is hereby provided for and of all carcasses and parts thereof, and of all meats and meat food products thereof, and of the sanitary conditions of all establishments in which such meat and meat food products hereinbefore described are prepared; and said inspectors shall refuse to stamp, mark, tag, or label any carcass or any part thereof, or meat food product therefrom, prepared in any establishment hereinbefore mentioned, until the same shall have actually been inspected and found to be not adulterated; and shall perform such other duties as are provided by this chapter and by the rules and regulations to be prescribed by said Secretary; and said Secretary shall, from time to time, make such rules and regulations as are necessary for the efficient execution of the provisions of this chapter, and all inspections and examinations made under this chapter, shall be such and made in such manner as described in the rules and regulations prescribed by said Secretary not inconsistent with provisions of this chapter.

21 U.S.C. § 678. **Non-Federal jurisdiction of federally regulated matters; prohibition of additional or different requirements for establishments with inspection services and as to marking, labeling, packaging, and ingredients; recordkeeping and related requirements; concurrent jurisdiction over distribution for human food purposes of adulterated or misbranded and imported articles; other matters**

Requirements within the scope of this chapter with respect to premises, facilities and operations of any establishment at which inspection is provided under subchapter I of this chapter, which are in addition to, or different than those made under this chapter may not be imposed by any State or Territory or the District of Columbia, except that any such jurisdiction may impose recordkeeping and other requirements within the scope of section 642 of this title, if consistent therewith, with respect to any such establishment. Marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this chapter may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any establishment under inspection in accordance with the requirements under subchapter I of this chapter, but any State or Territory or the District of Columbia may, consistent with the requirements under this chapter, exercise concurrent jurisdiction with the Secretary over articles required to be inspected under said subchapter I, for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of such an establishment, or, in the case of imported articles which are not at such an establishment, after their entry into the United States. This chapter shall not preclude any State or Territory or the District of Columbia from making requirement or taking other action, consistent with this chapter, with respect to any other matters regulated under this chapter.

U.S. Department of Agriculture
Food Safety and Inspection Service
Boulder District Office
665 S. Broadway, Suite B
Boulder, CO 80303
Telephone: (303) 497-5411
Facsimile: (303) 497-7306

August 25, 2000

Marsha Kreegar
Regulatory Affairs Superintendent
1505 Burlington Avenue
Fort Morgan, Colorado 80701

Dear Ms. Kreegar:

I received your request dated July 28 2000 to reduce carcass testing for E. coli O157:H7. Because of recent events involving zero tolerance and another confirmed positive for E. coli O157:H7 I am unable to approve your request. Although E. coli O157:H7 is not considered an adulterant in whole muscle cuts at this time, it is our suggestion that your HACCP plan be reassessed. Please let me know about your decision in this matter by September 1, 2000 and if you decide to reassess on what date the reassessment will be completed.

If you have any questions, please call me.

Sincerely,

/s/ Ronald J. Jones
Ronald K. Jones, District Manager

cc: Dr. Dale Hansen
Dr. Michael Finley
Scott Goltry, Excel Corporation

United Sates Department of Agriculture
Office of Public Affairs
News Division
Room 404-A
Washington, D.C. 20250

News Release No. 0092.93

Testimony

by

DR. H. RUSSELL CROSS
Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture

Before the State of Washington
Senate Committee on Agriculture

February 2, 1993

Madam Chairwoman. I am Dr. H. Russell Cross, Administrator of the U.S. Department of Agriculture's Food Safety and Inspection Service. With me is my assistant, Dr. Jill Hollingsworth. We very much appreciate the opportunity to be here today.

Before I begin, I want to reinforce the comments made by the secretary. We send our condolences to all family and friends affected by this tragedy. I also want you to know that the employees of FSIS are committed to pursuing every avenue to identify, contain and resolve this E. coli outbreak.

First, I will discuss what FSIS does. This agency is charged with inspecting meat and poultry products distributed in commerce to ensure they are safe and accurately labeled. FSIS carries out these inspections under the authority of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA).

We have 7,000 employees located throughout the United States inspecting meat and poultry. If a meat or poultry product is to be prepared at federally inspected establishments and/or distributed in commerce, an FSIS inspector inspects that product. Under the FMIA and the PPIA, we inspect the live animals before slaughter, and we inspect the carcasses after slaughter. Approximately 19 different inspection tasks are performed on each meat carcass.

As of the end of Fiscal Year 1991, 6,400 meat and poultry slaughtering and processing establishments received daily federal inspection. Over 117 million meat animals and over 6 billion birds were federally inspected during that year. Of the meat animals inspected during FY91, approximately 386,000 carcasses, or 1/3 of 1 percent, were condemned. For poultry, 75 million birds were condemned, or just over 1 percent. Carcasses are condemned for disease, contamination, or other adulteration during inspection.

Inspections of imported meat and poultry from approved countries are also performed by FSIS at 210 import inspection establishments located at borders or ports. In 1991, approximately 2.5 billion pounds of imported meat and poultry were passed for entry into the United States. Approximately 12 million pounds, or less than 1 percent of imported product, were refused entry to the U.S. due to failure to meet Federal requirements.

Another part of our food safety program involves laboratory analysis. Inspectors in the field are supported by laboratory testing for chemical and antibiotic residues, pathology diagnostics, processed product composition, and economic adulteration. We also analyze cooked meat and poultry products for microbiological contamination.

To conduct these laboratory analyses, FSIS operates three multidisciplinary laboratories and two contract laboratories, and accredits 215 private laboratories. We also have laboratories located at the Beltsville Agriculture Research Center, which are

methods development laboratories in pathology and microbiology. During Fiscal Year 1991, over 2.1 million analyses were performed on 470,573 samples at a cost of approximately $8.5 million.

Rapid in-plant screening tests provide another measure of safety. Results from these tests are available very quickly, thus assisting inspectors in making rapid food safety determinations about the product. Regrettably, there is no in-plant test developed and approved for microbiological testing of raw meat and poultry products. This is one of our highest research priorities and we expect significant progress in this area in the future.

FSIS also conducts enforcement and compliance activities to ensure that meat and poultry products in commerce are not adulterated, and are accurately labeled. In FY91, 63,416 compliance reviews were conducted. As a result of these reviews and other compliance activities, over 16 million pounds of meat and poultry were detained for noncompliance with meat and poultry laws. Twenty-nine recalls were conducted involving over 1.8 million pounds of product. In addition, 35 convictions were obtained against firms and individuals for violations of the FMIA and the PPIA.

The definition of "adulterated" under the meat and poultry acts has been construed by the Court of Appeals for the District of Columbia in American Public Health Association v. Butz, 511 F.2d 331 (D.C. Cir. 1974). In that case, the Court held that the presence of bacteria in raw meat and poultry does not constitute adulteration under the authorizing legislation. The Court has stated that Congress did not intend the prescribed official inspection legends on meat and poultry products to mean that the products were free from salmonellae and other bacteria because Congress did not intend that inspections include "microscopic examinations."

For this reason, raw meat with pathogens, even this product with E. coli 0157:H7, is not considered adulterated. Our review

and investigation have shown that all of the meat implicated in this outbreak was inspected and met the federal criteria for "safe raw meat." The bottom line is that raw meat contains bacteria, but proper cooking kills bacteria.

Although FSIS doesn't routinely perform microbiological tests on raw meat and poultry products, we have begun a baseline data collection program. However, as I have stated, products inherently contain bacteria, which does not cause them to be adulterated under the law.

Even if our statutes were changed, science is not advanced enough to make rapid microbiological testing feasible. Nor does a sample give a true picture of all the product – it is not possible to know if the "right" product has been sampled unless everything is sampled.

The simple fact is that proper cooking of meat and poultry products kill harmful bacteria. Cooking for the proper amount of time and at the State-mandated temperature would have prevented this outbreak.

As you might imagine, however, simply saying "cook meat and poultry properly" is not a satisfactory answer. Although the inspection system did not fail, we want to do more. We will be working with the U.S. Congress to develop intermediate and long term strategies that will ultimately take us to an inspection system that takes advantage of emerging technology and focuses on the various risks found in meat and poultry – including microbiological contaminants.

For the purposes of this hearing, I would like to focus on what we know today, what we can do today, and what we've already done.

FSIS was first notified by the Centers for Disease Control (CDC) of an outbreak of E. coli 0157:H7 in Washington State on January 18. In addition to immediately establishing a liaison with CDC, we contacted the State of Washington Department of Public Health to offer our assistance. We recognize that the

Department of Public Health has the lead in this investigation, but we have offered our assistance in conducting microbiological testing and in exercising our authority in federally inspected meat plants that might be involved. We also made contact with laboratories and individuals identified by CDC as playing a role in this investigation. The Washington Department of Public Health traced the most likely source of the bacteria to undercooked hamburger patties served at Jack-in-the-Box restaurants.

The production date of November 19, 1992, has been implicated by the State of Washington as the product used by Jack-in-the-Box that contained E. coli 0157:H7. It has a "use by" date of March 19, 1993. We requested that all product marked with this "use by" date be held by the parent company of Jack-in-the-Box, Foodmaker. That day's production continues to be held and has been the subject of microbiological testing by the State of Washington, USDA, and CDC. Should any other production date be implicated, we will hold that product also.

On January 19, we sent a team of FSIS Compliance Officers to a warehouse owned by Foodmaker in Tukwila, Washington, which was identified as the distributor of hamburger patties to Jack-in-the-Box. Compliance Officers were on site to monitor the return of product to the warehouse from Jack-in-the-Box and to ensure that the hamburger patties were properly detained in freezers. As soon as we learned that product was also being returned to another Foodmaker warehouse in the City of Commerce, California, we also sent our Compliance Officers there to monitor the product detention.

FSIS Compliance Officers have also been in touch with other state departments of health in states where the suspect product has been distributed. This includes the states of California, Nevada, Utah, Idaho, and Hawaii.

As you all know by now, the raw patties distributed by Foodmaker were produced at Vons Meat, a federally inspected

establishment in El Monte, California. Vons grinds the meat and makes the patties for Foodmaker. For November 19, 1992, we have been told all the product went to Foodmaker.

FSIS has dispatched a microbiologist and an epidemiologist to Vons to collect environmental and product samples. We also have sent FSIS Inspection Operations personnel to Vons to examine records and trace back possible sources of meat Vons used in its production. The samples we have collected from Foodmaker represent the production lots produced at Vons on November 19, 1992.

FSIS has confirmed laboratory results from 4 of the sampled lots. The actual number of bacteria found have been relatively low. We are continuing our lab tests and will conduct well over 1,000 analyses.

The positive test results from the November 19 product from Vons now leads our investigation to the plants that supplied meat to Vons, not only on November 19, but from October 1, 1992, to the present. It is difficult to recreate conditions and events that existed on November 19, but we are checking records to see if we can further track implicated product, trying to determine where the bacteria came from and how it got into the product.

For each supplier of Vons, we have sent Inspection Operations personnel to examine current sanitation records and general operating procedures. We are also focusing on the records of each of the suppliers to see if any breakdown in normal procedures occurred around the suspect date.

In addition, microbiologist teams will be taking samples from every supplier plant. At these supplier plants, we will be performing product sampling in addition to record checks. As with Vons, it is very difficult to recreate conditions as they existed months ago at these plants, but we want to cover every base possible.

While we continue our investigation on all fronts, there are other things FSIS is doing. We will expand our microbiological baseline data collection in beef animals. This survey will be ongoing. Results will give us the opportunity to establish the kind and amount of bacteria that are present today, and to determine if future changes in inspection procedures improve the microbiological profile of the carcasses.

We have held briefings for consumer and trade groups and Congressional staffers to make them aware of this outbreak and to let them know of the steps we are taking to end it. We have issued numerous consumer publications on how to safely cook, handle and store meat and poultry products. We are happy to make those available to anyone needing this type of information. We also operate a toll free Meat and Poultry Hotline that is staffed by home economists who answer basic or technical questions about food safety. Our Hotline number is 1-800-535-4555.

Although most of our inspectors and indeed most of our employees know of this E. coli outbreak, we issued an alert to all inspectors yesterday calling their attention to possible sources of this bacteria. Specifically, we are asking our inspectors to review all operations and procedures at the establishments they inspect to ensure that we are doing everything we can.

Additionally, the National Advisory Committee for Microbiological Criteria for Foods is meeting today. This Committee was formed in 1988, and has been extremely helpful to FSIS and the Secretary in making recommendations on controlling bacteria in the food supply. In light of this current outbreak, we have asked the Committee to take up the topic of E. coli 0151:H7 at its meeting today.

Other educational work on E. coli 0157:H7 is ongoing. It is frustrating to realize how little is really known about this pathogen. We are identifying experts and researchers to determine if there is any new scientific information available.

We are working with our sister agency, the Animal and Plant Health Inspection Service, to ascertain what information it might have about the occurrence of E. coli 0157:H7 in animals on the farm.

We do know that the group of bacteria called Escherichia coli are normally found in the intestines of warm-blooded animals such as food animals or humans. It can be found in contaminated water, and raw milk. It is not known at what level or dose the pathogen becomes hazardous.

In 1982, a rare and more virulent strain, called E. coli 0157:H7, was identified as the cause of two outbreaks of human illness. Since that time, there have been other reported outbreaks. Sources of E. coli 0157:H7 have included raw meat, water, unpasteurized milk, and low-acid apple cider.

E. coli 0157:H7 does not cause illness in animals. It can be carried in the intestinal tract of an animal, although it can also be found on the animal from contact with feces, and in the milk of dairy cows. Animals carrying this bacteria appear normal at the time of FSIS inspection, which is performed on each and every carcass. We do not know if the bacteria can be found elsewhere, such as circulating in the blood or lymphatic system. It can be transferred to the meat from the feces or milk. If there is any visible contamination on the meat, FSIS requires its removal. Also, all carcasses are thoroughly washed after inspection.

I cannot adequately express how distressed we in FSIS are that these tragic deaths and illnesses have occurred. But the fact is: bacteria, including pathogens, can be found on raw meat. This product is not adulterated. Science is not advanced enough to permit us to rapidly identify or control microbiological contaminants on raw meat, but E. coli 0157:H7 can be controlled by thorough cooking of raw meat.